Identifying Devices with UDI

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Agenda

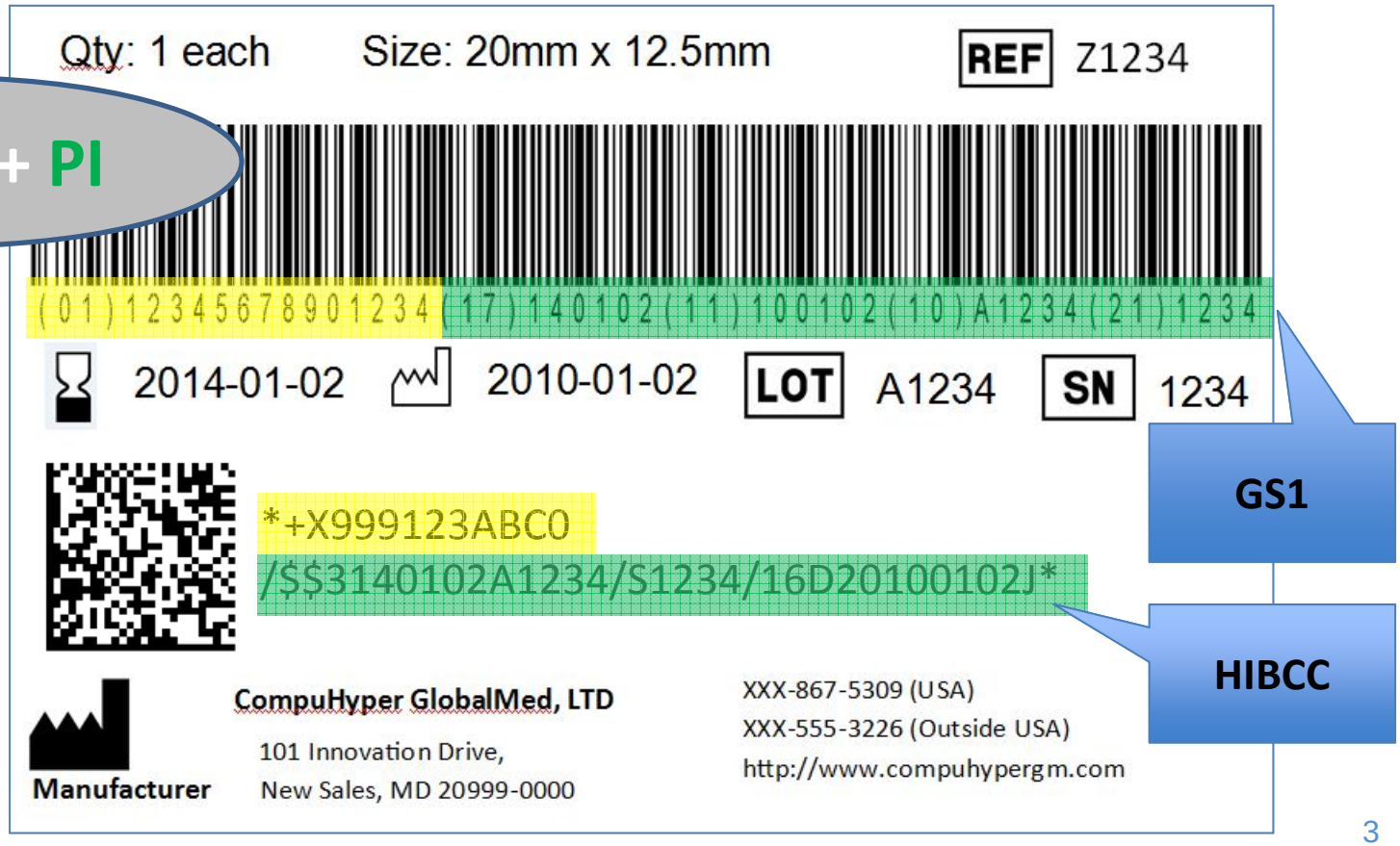
- What is UDI; What is AccessGUDID?
- Importance of UDI for patients
- Who are primary AccessGUDID users?
- Demo of AccessGUDID
- Resources
- Discussion/Questions

What is a UDI?

Required on the device label, packages or, in some cases, on the device itself

Code in plain text and machine readable format (AIDC)

UDI = DI + PI



AccessGUDID

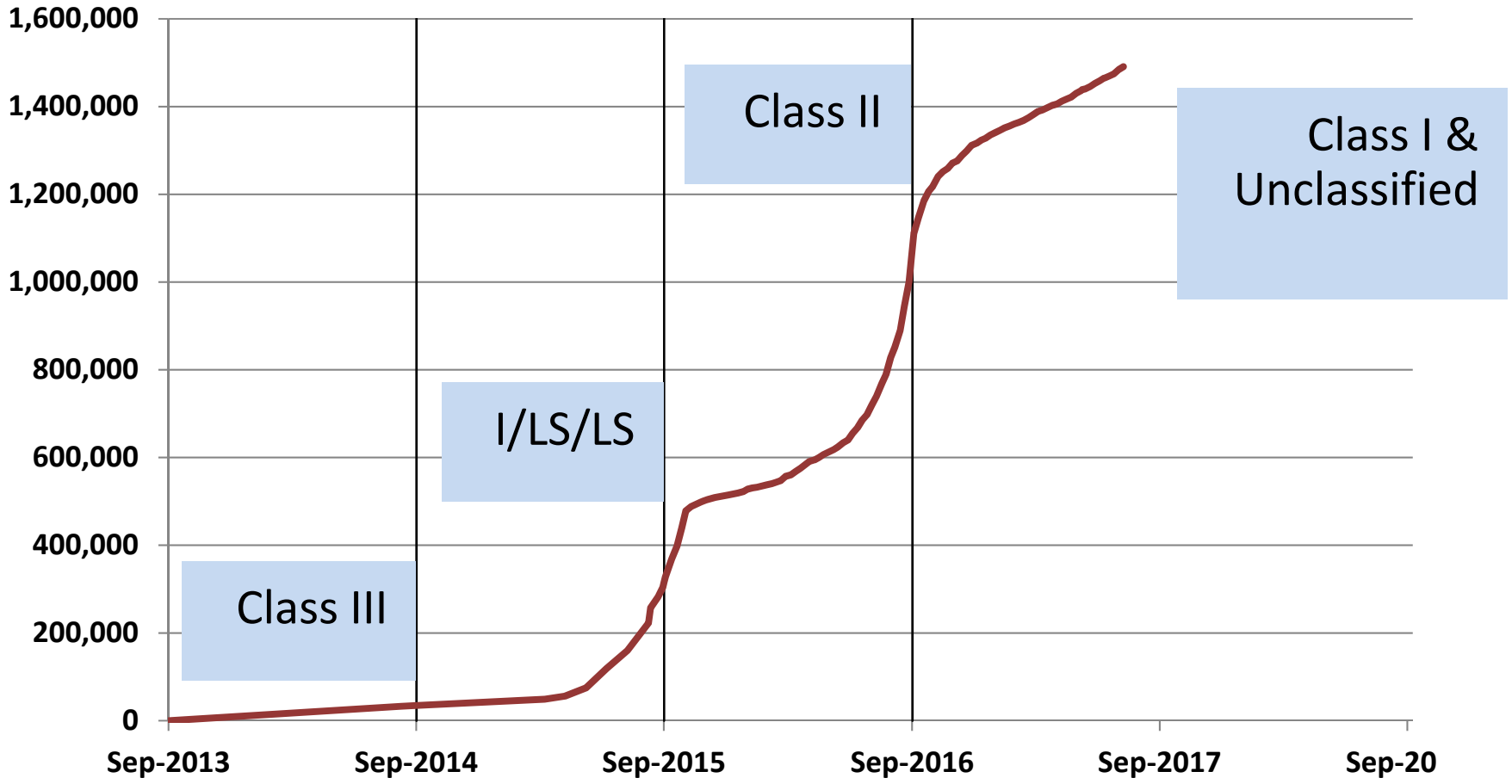
- **Standard reference source for FDA regulated devices**
- **Manufacturer submits once for multiple purposes**
- **Replace text, non-standard data with meta-data in AccessGUDID**

NLM and FDA Partnership

- Expertise with RxNorm, Vocabulary
- Daily Med website
- Support of ONC Health IT
  - EHR Certification Criteria
  - Meaningful Use
  - eCQM
- Existing healthcare web resources

GUDID Records and Submission Compliance Deadlines

Data Current as of August 1, 2017



UDI Regulatory Dates

Compliance Date	Must bear a UDI & submit data to GUDID	Direct Marking (for certain intended uses)
September 24, 2014	• Class III devices • Devices licensed under the PHS Act	
September 24, 2015	• Implantable, life-supporting and life-sustaining (I/LS/LS) devices	• LS/LS devices
September 24, 2016	• Class II devices	• Class III devices and devices licensed under the PHS Act
September 24, 2018	• Class I devices and unclassified devices	• Class II devices
September 24, 2020		• Class I devices and unclassified devices

Intend to extend

Goal of the UDI System

Use UDI and data from AccessGUDID to

accurately identify a device from manufacturer through distribution, use on a patient and as a means to evaluate devices over time

Successful UDI Implementation

- **Capturing, recording and transmitting UDI in all systems directly or indirectly involved in patient care**
- **Using UDI as the primary means of identifying a device**
- **Using AccessGUDID as the standard reference source linked to the DI of UDI**

IMPORTANCE OF UDI FOR PATIENTS

Patients and Cars

Medical Procedures [1]

1,000,000 Cardiac Catheterizations

719,000 Total Knee Replacements

332,000 Total Hip Replacements

New Cars Sold [2]

1,230,500 Hondas

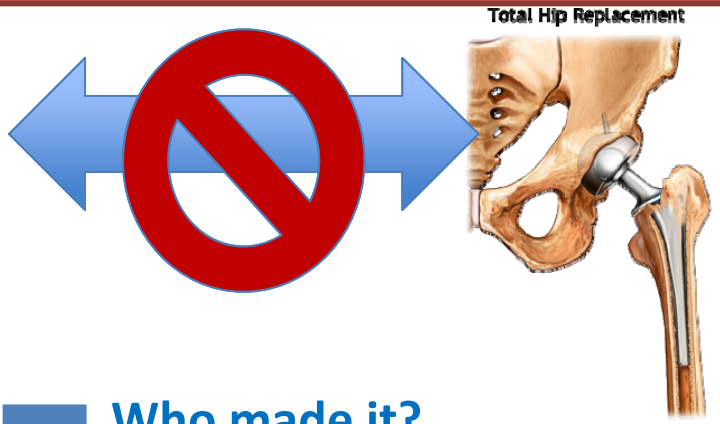
908,600 Nissans

358,500 Volkswagens

[1] Source: CDC/NCHS National Hospital Discharge Survey, 2010

[2] Source: WardsAuto - 2010 New Vehicle Sales

..Patient and Public Health Benefits



Patient

Who made it?
What model?
Has it been recalled?
Should I have it removed if it has been recalled?

Population

What is the performance compared to similar devices
What are problems/successes?
What was expected life?
Did it last longer than expected?

Linking UDI to Patients

Recording UDI in Health Records

Provider Milestones and Drivers

2015 Edition §170.315(a)(14) Implantable Device List

UDI in Common Clinical Data Set

January 2018 – Create and Transmit

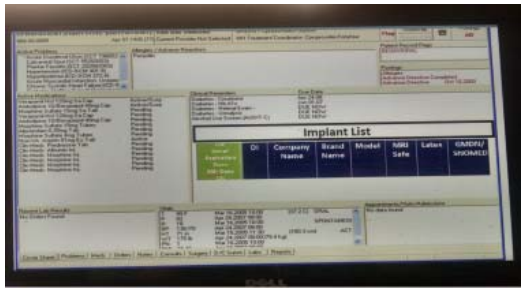
Patient Implantable Device list

ONC Certification Criteria

DI

Access GUDID Record

PI



Lot
Serial
Expiration Date
Mfr Date
DIC

Description (GMDN or SNOMED)

Company Name

Brand Name

Model

MRI Safe

Labeled as containing latex

Adoption in EHRs

Vendor	Software
Allscripts	Allscripts Professional EHR
Allscripts	Allscripts TouchWorks EHR
CureMD.com, Inc.	CureMD SMART Cloud
Epic Systems Corporation	EpicCare Ambulatory EHR Suite
Epic Systems Corporation	EpicCare Ambulatory EHR Suite
Epic Systems Corporation	EpicCare Inpatient EHR Suite
Epic Systems Corporation	EpicCare Inpatient EHR Suite
Cerner Corporation	FirstNet (Clinical)
MEDHOST	MEDHOST Enterprise
Henry Schein Medical Systems	MicroMD

Vendor	Software
Netsmart Technologies	myAvatar Certified Edition
McKesson	Paragon® for Hospitals 2015 Certified EHR
Cerner Corporation	PowerChart (Clinical)
SRS-Health	SRS EHR
Greenway Health, LLC	SuccessEHS
Allscripts	Sunrise Acute Care
Allscripts	Sunrise Ambulatory Care
Medical Transcription Billing Corporation (MTBC)	TalkEHR
Evident	Thrive EHR
Evident	Thrive Provider EHR

Adoption in EHRs

Vendor	Software
Allscripts	Allscripts Professional
A	
C	
Epic Systems Corporation	EpicCare Ambulatory EHR Suite
E C	
E Corporation	Suite
Epic Systems C	EpicCare Inpatient EHR
C	
MEDHOST	MEDHOST Enterprise
Henry Schein Medical Systems	MicroMD

Vendor	Software
Net Tec	
McKesson	Paragon® for Hospitals 2015 Certified EHR
Cer	
SRS	
Gre LLC	SuccessEHS
Alls	
Alls	
Medical Tra Cor	TalkEHR
Evi	
Evident	Thrive Provider EHR

Materials Management:
Improved Recall Management

Nursing:
Operating Room Efficiency

Clinical Engineers:
Improved Tracking

Quality:
Workflow Improvements

Information Systems:
Meaningful Use

Risk Management:
Patient Safety Projects

Researchers:
Medical Device Registries

Identifying Devices Today

GUDID		REGISTRY 1		REGISTRY 2	
Name	Value	Name	Value	Name	Value
Device Identifier	08714729805885				
Brand Name	Epic™ Vascular	Device Type	Epic Vascular Self Expanding Stent (120 CM shaft)	Desc.	Epic Vascular Stent System 9.0 mm x 100 mm
Company Name	BOSTON SCIENTIFIC CORPORATION	Device Mfr	Boston Scientific	Mfr	Boston Scientific Corporation
Catalog Number	H74939200091020	Product Number	39200-09102		
Model or Version	H74939200091020				

Supporting Device Evaluation

Enter data ONCE to support data capture and device evaluation

WL GORE

Vascular Quality Initiative

DEVICE: GORE VIABAHN Endoprosthesis (00733132614394)

DOWNLOAD: XML | JSON

VIEW ALL SECTIONS | CLOSE ALL SECTIONS

DEVICE IDENTIFIER (DI) INFORMATION

Brand Name: GORE VIABAHN Endoprosthesis
Version or Model: VBC050502
Catalog Number:
Company Name: W. L. Gore & Associates, Inc.
Device Description: No description.

Primary DI Number: 00733132614394
Issuing Agency: GS1
Device Count: 1

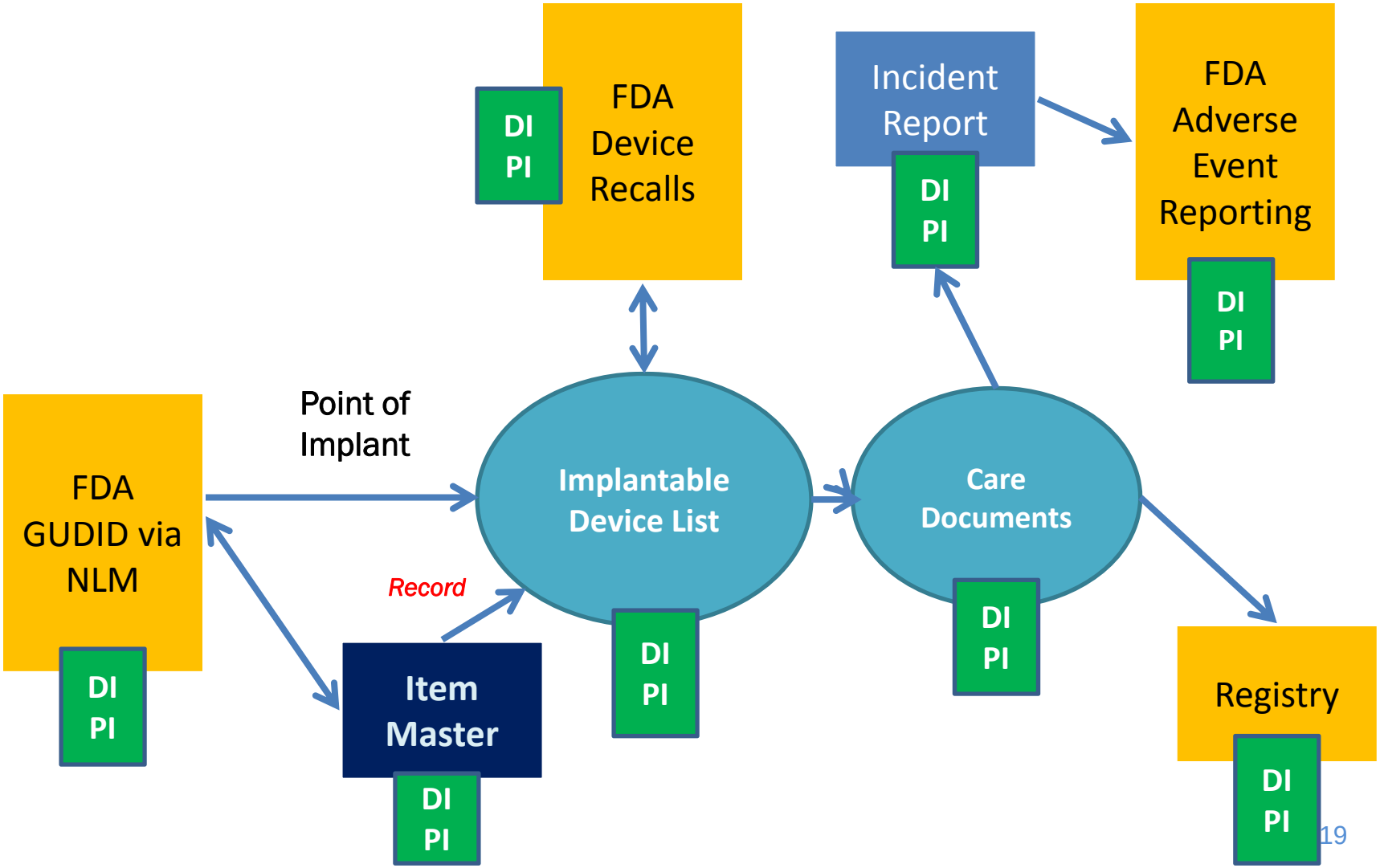
Treatment Type: Stent Graft
Product Number or DI: VBC
Manufacturer
Type
GUDID Diameter
GUDID Length

VBC050202 DI:00733132614387
VBC050502 DI:00733132614394
VBC051002 DI:00733132614400
VBC051502 DI:00733132614417
VBC060202 DI:00733132614424
VBC060501 DI:00733132614431
VBC060502 DI:00733132614448

Device 1

Treatment Type: Stent Graft
Product Number or DI: VBC050502 DI:00733132614394
Manufacturer: W. L. Gore & Associates, Inc.
Type: GORE VIABAHN Endoprosthesis
GUDID Diameter: 5 Millimeter
GUDID Length: 5 Centimeter

Linking Data across Data Sources



Features of AccessGUDID

- **Search** for a particular device using UDI on label
- **Use Web Services** to parse and/or pull standard AccessGUDID data into health IT systems (e.g. EHRs, Inventory Systems, Clinical Maintenance Management Systems, Charge Master, Registry)
- **Download** full set of AccessGUDID data for researching or analyzing a particular type of device

AccessGUDID Landing Page

U.S. NATIONAL LIBRARY OF MEDICINE

TOOLS AND RESOURCES

ACCESS GUDID

IDENTIFY YOUR MEDICAL DEVICE

peripheral artery stent

ABOUT AccessGUDID

The **Global Unique Device Identification Database (GUDID)** contains key device identification information submitted to the FDA about medical devices that have **Unique Device Identifiers (UDI)**.

The FDA is establishing the unique device identification system to adequately identify devices sold in the U.S.- from manufacturing through distribution to patient use. You can use AccessGUDID to search for specific medical devices or download all the GUDID data at once. AccessGUDID also offers RSS feeds and APIs to connect you directly to the data.

MORE INFO

ABOUT UDI

ABOUT GUDID

NEWS

AccessGUDID News

Posted: June 1, 2017

New: Output Full Records in Linkable Tables

DOWNLOAD

Download Data

Download the latest full releases and update files provided to the NLM by the FDA.

API

API Documentation

Resources for application developers to get the most out of AccessGUDID.

RSS

RSS Documentation

Subscribe to RSS feeds to receive the latest files.

HELP

Help using AccessGUDID

Searching AccessGUDID

Downloading Release Files

NLM Web Guidelines

Exporting Results

U.S. NATIONAL LIBRARY OF MEDICINE

TOOLS AND RESOURCES

ACCESS GUDID

IDENTIFY YOUR MEDICAL DEVICE

peripheral artery stent

HOME | ABOUT | NEWS | API | DOWNLOAD | HELP

SEARCH RESULTS FOR: peripheral artery stent (4381 results)

EXPORT RESULTS

FILTERS

SORT BY

EXPORT RESULTS

SEARCH SUMMARY

XML

CSV

XLS

JSON

FULL RECORD

DELIMITED .TXT FILES

Company Name

COOK INCORPORATED (4381)

Brand Name

GMDN Term

FDA Product Code Name

FDA Product Code

Device Packaged As Sterile

Sterilization Prior To Use

Issuing Agency

Advance - 00827002441477
ATB Advance, PTA Dilatation Catheter
Company Name: COOK INCORPORATED
Version or Model: G44147

Advance - 00827002423862
ATB Advance, PTA Dilatation Catheter
Company Name: COOK INCORPORATED
Version or Model: G42386

Advance - 00827002423794
ATB Advance, PTA Dilatation Catheter
Company Name: COOK INCORPORATED
Version or Model: G42379

Advance - 00827002423718
ATB Advance, PTA Dilatation Catheter
Company Name: COOK INCORPORATED
Version or Model: G42371

Advance - 00827002312128
ATB Advance, PTA Dilatation Catheter

Main Search Results

ACCESS GUDID
IDENTIFY YOUR MEDICAL DEVICE

Enter Device Identifier, Name, or Company

HOME | ABOUT | NEWS | API | DOWNLOAD | HELP

DEVICE: Advance (00827002441477)

DOWNLOAD: XML | JSON PRINT

VIEW ALL SECTIONS | CLOSE ALL SECTIONS

DEVICE IDENTIFIER (DI) INFORMATION

Brand Name: Advance
Version or Model: G44147
Catalog Number: ATB5-35-120-14-4.0
Company Name: COOK INCORPORATED
Device Description: ATB Advance, PTA Dilatation Catheter

Primary DI Number: 00827002441477
Issuing Agency: GS1
Device Count: 1

CLOSE

DEVICE CHARACTERISTICS

DEVICE STATUS

ALTERNATIVE AND ADDITIONAL IDENTIFIERS

CUSTOMER CONTACT [?]

Phone: +1(812)330-5494
Email: sharedservices@cookmedical.com

CLOSE

Device Characteristics

close

DEVICE CHARACTERISTICS

What MRI safety information does the labeling contain?	Labeling does not contain MRI Safety Information
Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437):	No
Device labeled as "Not made with natural rubber latex":	No
For Single-Use:	Yes
Prescription Use (Rx):	Yes
Over the Counter (OTC):	No
Kit:	No
Combination Product:	No
Human Cell, Tissue or Cellular or Tissue-Based Product (HCT/P):	No

GMDN [?]

GMDN Names and Definitions: © Copyright GMDN Agency 2015. Reproduced with Permission from the GMDN Agency.

GMDN Preferred Term Name	GMDN Definition
Peripheral angioplasty balloon catheter, basic	A sterile, non-drug-eluting, flexible tube designed for percutaneous transluminal angioplasty (PTA) to dilate a stenotic peripheral (i.e., non-cerebral, non-coronary) artery by controlled inflation of a distensible balloon(s) at its distal tip; it may also be intended for positioning and expansion of a stent/stent-graft. It is available as an over-the-wire (OTW) type with multiple lumens, or a rapid exchange (RX) type with a single lumen. Some types may include microsurgical blades (atherotomes) to score the plaque. This is a single-use device.

More Device Characteristics

FDA PRODUCT CODE [?]

Product Code	Product Code Name
DQY	CATHETER, PERCUTANEOUS

CLOSE

STERILIZATION

Device Packaged as Sterile: Yes
Requires Sterilization Prior to Use: No

Sterilization Method [?]
No Sterilization Methods Found

CLOSE

STORAGE AND HANDLING [?]

Storage and Handling
Special Storage Condition, Specify: Store in dark, dry, cool place.

CLOSE

CLINICALLY RELEVANT SIZE [?]

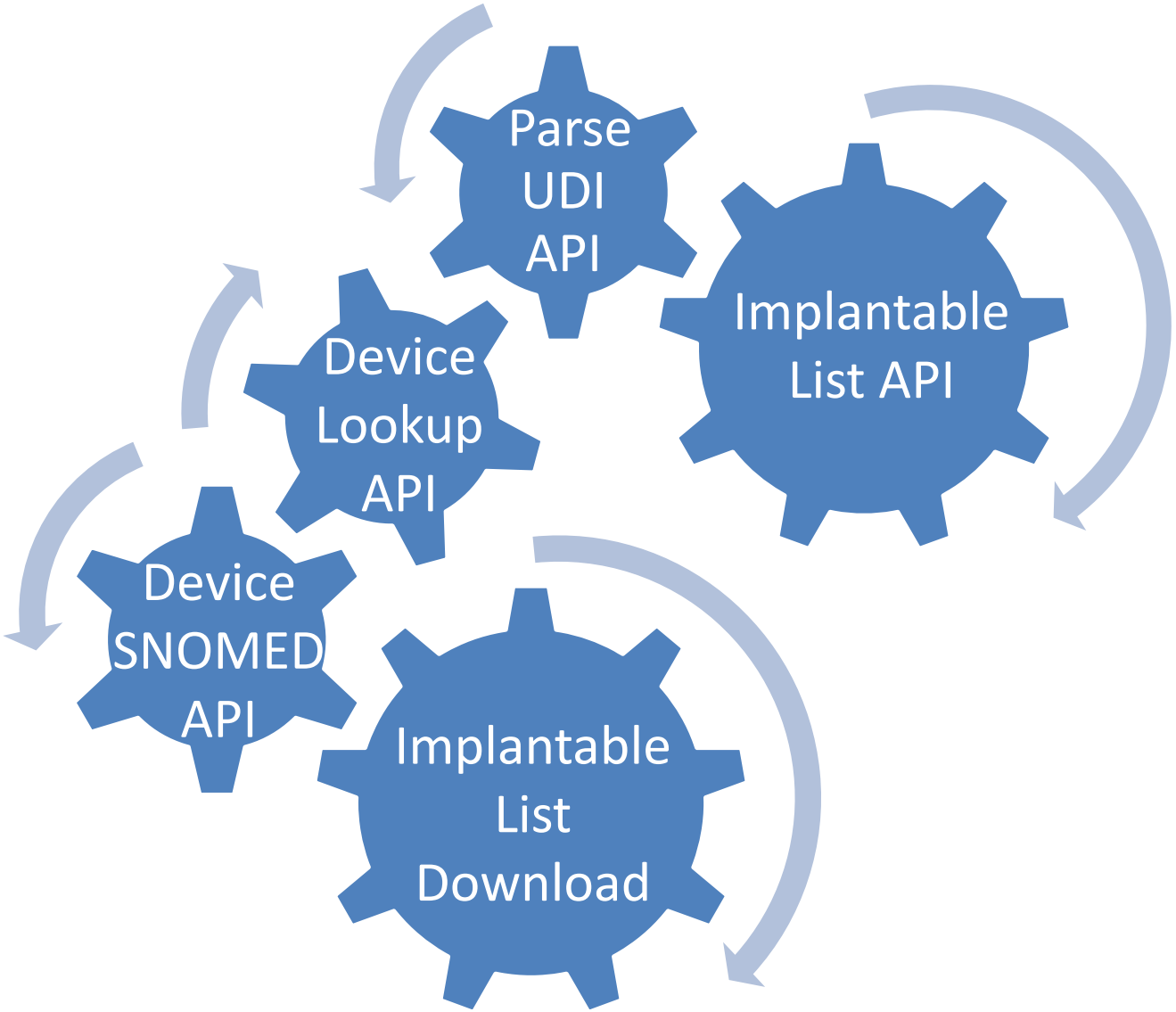
Size Type Text
No Device Sizes

CLOSE

DEVICE STATUS

Commercial Distribution Status: In Commercial Distribution
DI Record Publish Date: September 24, 2016

Web Services



Implantable List API

Implant List API

- Resources Home
- ⚠ Notice

Feeds

- RSS

Developers

- **Implantable List API**
- Implantable List Download
- Device Lookup API
- Device SNOMED API
- Parse UDI API
- + Importing Delimited Device Files

GET /devices/implantable/list

Returns a paginated list of devices that are implantable or accessories to an implant system along with some metadata about the device. If provided a UMLS single-use ticket, it also returns the SNOMED data.

RESOURCE INFORMATION

format	URL
JSON	https://accessgudid.nlm.nih.gov/api/v1/devices/implantable/list.json
XML	https://accessgudid.nlm.nih.gov/api/v1/devices/implantable/list.xml

PARAMETERS

parameter	type	default	description
ticket	String	null	The single-use ticket used to access UI valid ticket will allow the SNOMED data returned in addition to all the other infor normally returned without a ticket. Example Value: ST-210847-HwTfbMTY100CWN

Implantable List Download

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GET /devices/implantable/download

Returns a ZIP file that contains a CSV and an equivalent XLSX file. These files are flattened versions of the /devices/implantable/list API. If provided a UMLS single-use ticket, it also returns the SNOMED data.

RESOURCE INFORMATION

format	URL
`ZIP` Contains `CSV` and `XLSX` files	`https://accessgudid.nlm.nih.gov/api/v1/devices/implantable/download`

PARAMETERS

parameter	type	default	description
`ticket`	`String`	`null`	The single-use ticket used to access UMLS. A valid ticket will allow the SNOMED data to be returned in addition to all the other information normally returned without a ticket **Example Value:** `ST-210847-HwTfbMTY100CWNe2owFF-cas` For information on how to generate a single-use ticket, please see the page on Generating UMLS Tickets.

Device Lookup API

Device Lookup API

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Developers

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GET /devices/lookup

Returns a single device record in either the original XML format that AccessGUDID receives from the FDA, or a JSON version of that record. A device identifier is required to receive a response.

RESOURCE INFORMATION

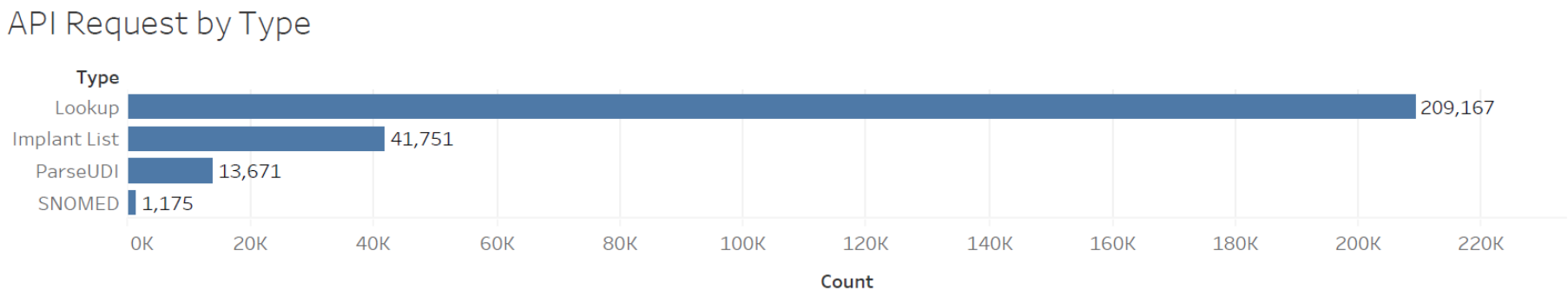
format	URL
`JSON`	https://accessgudid.nlm.nih.gov/api/v1/devices/lookup.json
`XML`	https://accessgudid.nlm.nih.gov/api/v1/devices/lookup.xml

PARAMETERS

Either a `di` or a `udi` must be provided.

parameter	type	description
`di`	`String`	The Device Identifier string unique to a specific device
`udi`	`String`	The full Unique Device Identifier string for a device

Lookup API is Most Used

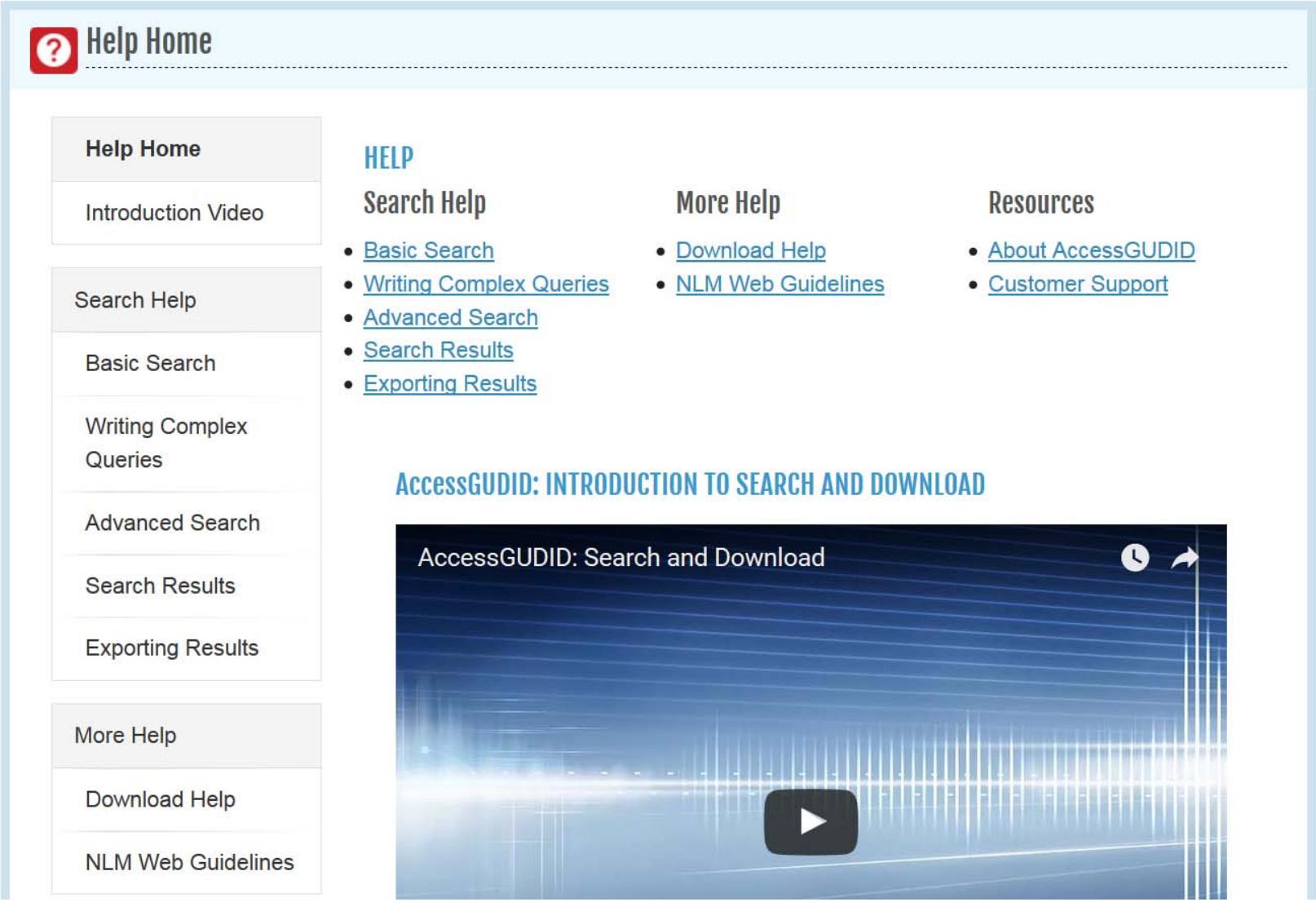


Sum of Count for each Type. The marks are labeled by sum of Count.

Upcoming Enhancements

- Additional GUDID Fields
- Enhanced Customer Support
- Data Quality Issue Reporting
- Graphical Data Insights Shown in Real Time

Training Resources



Promoting AccessGUDID

- Educate on UDI and encourage use of AccessGUDID across library user groups – IT, researchers, Biomedical Engineers, Supply Chain, Clinicians
- Promote participation in UDI user groups – EHR vendors, AHRMM Learning UDI Community
- Incorporate and add to UDI Resource links
  - Maintain a bibliography of UDI and National Evaluation System references
  - Provide feedback on resources needed to improve UDI System success

UDI Resources

- FDA UDI Website
  - AccessGUDID, UDI Help Desk, Regulations and Guidance, Benefits of UDI
- Office of National Coordinator for Health IT (ONC)
  - Implantable Device List
  - Common Clinical Data Set
  - Meaningful Use
- Office of the Assistant Secretary for Planning and Education (ASPE)
  - Strategically Coordinated Registry for Women's Health Technologies and other projects

UDI Resources

- Association for Healthcare Resources and Materials Management (AHRMM) Learning UDI Community
  - UDI Resources
  - Workgroups to address adoption challenges
- Medical Device Epidemiology Network (MDEPINET)
  - UDI and National Education System education, case studies, bibliographies
- Medical Device Innovation Consortium National Evaluation System for health Technology (NEST) Coordinating Center
  - Status of Center
  - Demonstration projects

Summary

- **UDI –** standard that opens up ability to scan and identify devices more accurately in electronic supply chain, device maintenance and clinical sources
- **AccessGUDID** - reference data source that associates DI of UDI with standard meta-data that can be shared across care continuum
- **Value** – potential value of UDI system crosses broad range of stakeholders and, ultimately improves patient and device safety and innovation